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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	-			
	09/885,439	IVORY ET AL.	4.			
Office Action Summary	Examiner	Art Unit	<del>-</del>			
	Jeffrey T. Barton	1753				
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet w	with the correspondence address	:s			
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a rep If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailir earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a ply within the statutory minimum of the will apply and will expire SIX (6) MC e. cause the application to become A	a reply be timely filed  irty (30) days will be considered timely.  DNTHS from the mailing date of this commur	nication.			
Status						
<ol> <li>Responsive to communication(s) filed on <u>02 A</u></li> <li>This action is <b>FINAL</b>. 2b) This</li> <li>Since this application is in condition for allowed closed in accordance with the practice under the practice under the practice of the</li></ol>	s action is non-final. ance except for formal ma		rits is			
Disposition of Claims						
4)	wn from consideration. 77 is/are rejected.	oplication.				
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine	cepted or b) objected to drawing(s) be held in abeya tion is required if the drawing	ince. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1. <sup>2</sup>				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list-of-the certified copies-not received.						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 20011001.	Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application (PTO-152) 				

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1-3, 8, 17, 47-51, 57, 63, 64, and 69-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Koegler et al. (*Biotechnol. Prog.* 1996)

Addressing claims 1 and 70, Koegler et al disclose a device for focusing charged solute (Figure 7), comprising: a first chamber for receiving a liquid medium (Inside the dialysis tubing) having an inlet and outlet for fluid flow into and out of the chamber (Indicated by arrows "Buffer and Protein" and "To Detector & Collection"); a second chamber (Outside the dialysis tubing) comprising an electrode array (Two electrodes is a plurality, see definition in specification Page 7, line 33 - Page 8, line 1; also see Future Directions section) having an inlet and outlet for fluid flow into and out of the chamber (Indicated by arrows, Recirculating Electrolyte (& Cooling)); a porous material separating the first and second chambers (dialysis tubing, Equipment section, 1st paragraph); and means for dynamically controlling the voltage applied to the electrode array (Future Directions section)

Addressing claim 2, Koegler et al disclose the first and second chambers being in liquid communication. (Dialysis tubing allows aqueous liquid flow)

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Addressing claim 3, Koegler et al disclose the first chamber being in electrical communication with the electrode array. (Figure 2 and caption)

Addressing claim 8, Koegler et al disclose the electrode array generating an electric field gradient profile. (Figure 2)

Addressing claim 17, Koegler et al disclose the device comprising first and second conduits for introducing and exiting fluid media from the first chamber. (Figure 7, indicated by arrows; details in 2<sup>nd</sup> - 4<sup>th</sup> paragraphs of Equipment section)

Addressing claims 47 and 71, Koegler et al disclose a method for focusing a charged solute in a fluid medium comprising: introducing a charged solute into a fluid medium, wherein the fluid medium is contained in a device according to claim 1 (Experiments section, 1<sup>st</sup> - 4<sup>th</sup> paragraphs); and applying an electric field gradient to the charged solute in the fluid medium to cause the charged solute to focus in a region of the medium. (Experiments section, 3<sup>rd</sup> and 4<sup>th</sup> paragraphs)

Addressing claim 48, Koegler et al disclose the first liquid being a buffer.

(Experiments section, 3<sup>rd</sup> paragraph) They also refer to the flow of this buffer as elution.

(5<sup>th</sup> paragraph)

Addressing claim 49, Koegler et al disclose the second liquid being a coolant buffer (Figure 7, arrow label)

Addressing claims 50 and 51, Koegler et al disclose the first liquid being either the same or different from the second liquid. (Experiments section, 2<sup>nd</sup> paragraph; describe buffer mismatch and contrast corresponding results to results without the mismatch (i.e. identical buffers))

Addressing claims 57 and 64, Koegler et al disclose a method for focusing a charged solute or separating charged solutes comprising: applying a charged solute to a fluid medium; applying a hydrodynamic force to the solute in the fluid medium; and opposing the hydrodynamic force with an electric field gradient to provide solutes focused in the fluid medium in order of their electrophoretic mobilities (All in Separation of Myoglobins section, 2<sup>nd</sup> paragraph); wherein the electric field gradient is generated by an electrode array (Figure 7; Future Directions section), and wherein the electric field gradient is dynamically controlled (Future Directions section)

Addressing claims 63 and 69, Koegler et al disclose focusing and separation of proteins. (Separation of Myoglobins section)

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 6. Claims 4, 5, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koegler et al (*Biotechnol. Prog.* 1996) in view of Ivory et al (U.S. Patent No. 5,298,143).

Koegler et al disclose devices and methods as described above in addressing claims 1 and 57. Relevant to claim 5, they also disclose individual control of electrodes in their array. (Future Directions section, "independent electrodes")

Koegler et al do not explicitly disclose a device or method in which a plurality of electrodes is arranged linearly along an axis parallel to the direction of migration of the solute. However, they do disclose using arrays of independent electrodes arranged outside the separation chamber. (Future Directions section)

Ivory et al disclose a similar gradient focusing device (Figure 16), which uses a linear array of electrodes (422-424) arranged along an axis parallel to the direction of solute migration.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Koegler et al by incorporating an array of electrodes arranged linearly along the outside of the separation chamber, as taught by Ivory et al, because it would provide greater control of the electric field gradient, and Koegler et al suggested the use of such electrode arrays.

7. Claims 72, 74, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koegler et al (*Biotechnol. Prog.* 1996) in view of Ivory et al (U.S. Patent No. 5,298,143).

Relevant to claim 72, Koegler et al disclose a system for focusing a solute, comprising: a device according to claim 1 (See paragraph 2 above); an analytical instrument (Spectrophotometer; Equipment section, 4<sup>th</sup> paragraph); and an interface intermediate the device and the analytical instrument (Rainin flangeless fittings, Equipment section, 4<sup>th</sup> paragraph)

Relevant to claim 76, Koegler et al disclose the analytical instrument being an optical detection device. (Spectrophotometer)

Koegler et al do not explicitly disclose the system comprising a controller comprising a plurality of controller units in communication with the electrode array (Claim 72), nor do they disclose the controllers dynamically monitoring and setting the voltage at each electrode in response to signals from an operator. (Claim 74)

Ivory et al disclose a similar gradient focusing device (Figure 16) which uses a controller comprising a plurality of controller units in communication with the electrode

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array. (Column 8, line 55 - Column 9, line 53) Relevant to claim 74, they also disclose the controller dynamically monitoring and setting the voltage in response to signals from an operator. (Column 9, lines 26-31)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Koegler et al by using a controller with a plurality of controller units in communication with the electrodes, as taught by Ivory et al, because it would provide the independent electrode control described by Koegler et al. (Future Direction section)

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to provide a controller that dynamically monitors and sets the voltage in response to operator signals, as taught by Ivory et al, because it would provide convenient, precisely controlled device operation.

8. Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koegler et al (*Biotechnol. Prog.* 1996) and Ivory et al (U.S. Patent No. 5,298,143) as applied to claim 72 above, and further in view of Hurd. (U.S. Patent No. 4,670,119)

Koegler et al and Ivory et al disclose a combined system as described above in addressing claim 72.

Neither Koegler et al nor Ivory et al disclose a third chamber with a second electrode array and fluid inlets and outlets, separated from the first-chamber by a second porous material, wherein the first and second porous materials are on opposite sides of the first chamber, and electrodes in the two arrays form pairs.

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Hurd discloses a similar focusing device (Figure 5), in which there are two electrode arrays (22) disposed in an electrolyte chamber (10) each array being separated from the separation chamber (20) by a porous membrane (24), with electrodes in the array forming pairs (Column 9, lines 64-67), with the porous membranes (24) being on opposite sides of the separation chamber.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combined system of Koegler et al and Ivory et al by providing an electrode geometry (i.e. pairs opposite each other, separated from the separation channel by oppositely-disposed membranes) as taught by Hurd, because it would provide an electric field gradient uniform in the channel cross section without requiring varying chamber width. It would also have been obvious to separate the electrode arrays into different chambers, because it would allow simpler construction of longitudinal inlets and outlets to the separation channel, of the type disclosed by Koegler et al (Figure 7).

9. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koegler et al (*Biotechnol. Prog.* 1996) and Ivory et al (U.S. Patent No. 5,298,143) as applied to claim 72 above, and further in view of Arai.

Koegler et al and Ivory et al disclose a combined system as described above in addressing claim 72.

Neither Koegler et al nor Ivory et al disclose a controller that sets the voltage at each electrode in response to signals from an analytical instrument.

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Arai discloses an electrophoretic device comprising a controller that provides voltages based on signals from analytical devices. (Column 5, line 21 - Column 6, line 22)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combined system of Koegler et al and Ivory et al by providing a controller that provides voltage control in response to signals from analytical devices, as taught by Arai, because it would allow system operation with minimal requirements for operator input.

10. Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koegler et al (*Biotechnol. Prog.* 1996) and Ivory et al (U.S. Patent No. 5,298,143) as applied to claim 72 above, and further in view of Cabilly et al.

Koegler et al and Ivory et al disclose a combined system as described above in addressing claim 72. Koegler et al also disclose monitoring the progress of a separation using images taken at different times during the operation. (Figure 8)

Neither Koegler et al nor Ivory et al disclose the use of a video camera as an analytical instrument.

Cabilly et al disclose an electrophoresis apparatus that uses a video camera to record results of separations. (Column 4, lines 42-45)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combined system of Koegler et al and Ivory et al by recording the progress of a separation with a video camera, because it would give a full

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record of the separation progress and provide continuous data of the kind reported by Koegler et al. (Figure 8)

### **Double Patenting**

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

- 12. Claims 57 and 64 are rejected under 35 U.S.C. 101 as claiming the same invention as those of claims 38 and 42 of prior U.S. Patent No. 6,277,258, respectively. This is a double patenting rejection.
- 13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-5, 8, 17, and 70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-12 and 21 of U.S. Patent No. 6,277,258 in view of either Ivory et al (U.S. 5,298,143) or Koegler et al (*Biotechnol. Prog.* 1996).

Claim 7 of U.S. Patent No. 6,277,258 claims a device including all limitations of instant claims 1 and 70 (First and second chambers defined by the troughs and the membrane), except the means for dynamically controlling the voltage applied to the electrode array.

Claims 8-12 and 21 of U.S. Patent No. 6,277,258 claim the same limitations given by instant claims 2-5, 8, and 21.

lvory et al disclose a means for dynamically controlling the voltage applied to an electrode array in a similar device. (Column 8, line 55 - Column 9, line 53)

Koegler et al also disclose a means for dynamically controlling the voltage applied to an electrode array in another similar device. (Future Directions section)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Claims 7-12 and 21 of U.S. Patent No. 6,277,258 by providing a means of dynamic control of the electrode voltages, as taught by either Ivory et al or Koegler et al, because it would provide facile and precise control of electric field gradients in the device.

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15. Claims 47-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-36 of U.S. Patent No. 6,277,258 in view of either Ivory et al (U.S. 5,298,143) or Koegler et al (*Biotechnol. Prog.* 1996).

Claim 32 of U.S. Patent No. 6,277,258 claims a device including all limitations of instant claim 47 (First and second chambers defined by the troughs and the membrane), except the means for dynamically controlling the voltage applied to the electrode array.

Claims 33-36 of U.S. Patent No. 6,277,258 claim the same limitations given by instant claims 48-51.

lvory et al disclose a means for dynamically controlling the voltage applied to an electrode array in a similar device. (Column 8, line 55 - Column 9, line 53)

Koegler et al also disclose a means for dynamically controlling the voltage applied to an electrode array in another similar device. (Future Directions section)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Claims 32-36 of U.S. Patent No. 6,277,258 by providing a means of dynamic control of the electrode voltages, as taught by either lvory et al or Koegler et al, because it would provide facile and precise control of electric field gradients in the device.

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16. Claim 58 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 37 of U.S. Patent No. 6,277,258 in view of either Ivory et al (U.S. 5,298,143) or Koegler et al (*Biotechnol. Prog.* 1996).

Claim 37 of U.S. Patent No. 6,277,258 claims a device including all limitations of instant claim 58 except for dynamic control of the electric field gradient

Ivory et al disclose a means for dynamically controlling an electric field gradient in a similar device. (Column 8, line 55 - Column 9, line 53)

Koegler et al also disclose a means for dynamically controlling an electric field gradient in another similar device. (Future Directions section)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Claim 37 of U.S. Patent No. 6,277,258 by providing a means of dynamic control of the electric field gradient, as taught by either lvory et al or Koegler et al, because it would provide facile and precise control of an ongoing separation.

17. Claims 63 and 69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38 and 42 of U.S. Patent No. 6,277,258, as applied to instant claims 57 and 64 above, and further in view of claim 25 of U.S. Patent No. 6,277,258. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 25 shows the utility of the devices and methods of U.S. Patent No. 6,277,258 in separating the molecules listed in the instant claims.

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18. Claim 71 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of U.S. Patent No. 6,277,258. Although the conflicting claims are not identical, they are not patentably distinct from each other because the recitation of lines 5-21 of claim 32 defines a device equivalent to that of lines 4-10 of the instant claim.

19. Claims 72, 74, and 76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al (U.S. 5,298,143) and Koegler et al (*Biotechnol. Prog.* 1996).

Claim 7 of U.S. Patent No. 6,277,258 claims a device including all limitations of instant claim 72 (First and second chambers defined by the troughs and the membrane), except the controller, analytical instrument, and interface limitations.

Claim 7 also does not explicitly disclose a controller that dynamically monitors and sets the voltage at the electrodes in response to signals from the operator (Claim 74), or a system that includes an optical or potentiometric analytical device. (Claim 76)

Ivory et al discloses a controller comprising a plurality of controller units (Figure 17) in communication with an electrode array of a similar gradient focusing device. This controller dynamically monitors and sets the voltage at the electrodes in response to signals from an operator. (Column 9, lines 26-31)

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Koegler et al disclose an optical analytical instrument and interface of this instrument with the device. (Spectrophotometer and fittings, Equipment section 4<sup>th</sup> paragraph)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Claim 7 of U.S. Patent No. 6,277,258 by providing a controller with plural controller units in communication with the electrode array, that dynamically monitors and sets the voltage under user control, as taught by Ivory et al, because it would provide precise control of the separation device.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Claim 7 of U.S. Patent No. 6,277,258 and Ivory et al by providing an optical analytical instrument interfaced with the separation device, as taught by Koegler et al, because it would allow accurate removal of fractions of analytes from the chamber.

20. Claim 73 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al and Koegler et al as applied to claim 72 above, and further in view of Hurd. (U.S. 4,670,119)

Claim 75 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al and Koegler et al as applied to claim 72 above, and further in view of Arai.

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Claim 77 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al and Koegler et al as applied to claim 72 above, and further in view of Cabilly et al.

The material disclosed by the combination of claim 7 of U.S. Patent No. 6,277,258 with Ivory et al and Koegler et al is as described above in paragraph 19.

The material not disclosed by this combination; the disclosures of Hurd, Arai, and Cabilly; and the motivation for combination with these references are all as described above in paragraphs 8, 9, and 10.

#### Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

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JTB September 29, 2004

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